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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/812,544 | 03/29/2004 | Claudio Bucolo | P03314 | 3426 |
| 23702 7590 12/21/2006 Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701 | | | EXAMINER HENRY, MICHAEL C | |
| | | | ART UNIT 1623 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | | MAIL DATE | DELIVERY MODE |
| 3 MONTHS | | | 12/21/2006 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/812,544

Applicant(s)

BUCOLO ET AL.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-12 and 26-75 is/are pending in the application.
- 4a) Of the above claim(s) 26-39 and 54-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-12,40-53 and 69-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/14/04 & 11/13/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The following office action is a responsive to the amendment filed on 11/02/06 in which a provisional election was made without traverse to prosecute the invention of Group I, claims 1-12, 40-53. The response has the following effect:

1. Claims 1-3, 6-12, 40-53, 69-75, the invention of Group I are prosecuted by the examiner. Claims 4-5 and 13-25 have been canceled. Claims 26-39, 54-68 are withdrawn. New claims 69-75 have been added.
2. The responsive is contained herein below.

Claims 1-3, 6-12, 26-75 are pending in the application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 71, 72, 74 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 71, 72, 74 and 75 recite the phrase "further comprises 1 mM to 40 mM".

However, the claim is indefinite because it is unclear which compound, substance or component concentration is being referred to as having 1 mM to 40 mM.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-12, 40-53, 69, 70, 73 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yamamoto et al. (JP 62122671 A2).

In claim 1, applicant claims a viscoelastic composition comprising water, 0.6%w/v to 4%w/v of hyaluronic acid or a salt thereof and 0.1% w/v to 2%w/v of hydroxypropylmethylcellulose, wherein the viscoelastic composition has a pseudoplasticity index from 160 to 5000, and a ratio of hydroxypropylmethylcellulose to hyaluronic acid or a salt thereof from 0.1 to 1.

Yamamoto et al. disclose applicants' claimed viscoelastic composition comprising water, 1.0-2.0 w/v% of hyaluronic acid or a salt thereof and 1.0-2.0 w/v% of hydroxypropylmethylcellulose, and a ratio of hydroxypropylmethylcellulose to hyaluronic acid or a salt thereof 1 (see abstract). Yamamoto et al. do not explicitly disclose the physical characteristics that pertain to the pseudoplasticity index of their prepared composition. But, the silence of Yamamoto et al. do not mean that their composition do not have the same pseudoplasticity index or physical characteristics. Yamamoto et al. anticipates the claims if their composition has the same claimed pseudoplasticity index. Yamamoto et al. renders the claims as being obvious if their composition has a pseudoplasticity index that is substantially close to the

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pseudoplasticity index of applicant's claimed composition. Claims 2-3 which are drawn to the composition of claim 1, wherein the hyaluronic acid and hydroxypropylmethylcellulose have specific average molecular weights ranges, are also encompassed by this rejection since although Yamamoto et al.'s is silent about the average molecular weight of their hyaluronic acid and hydroxypropylmethylcellulose, their composition may well have the same or substantially close average molecular weights of hyaluronic acid and hydroxypropylmethylcellulose as applicant's composition (see abstract). Similarly, claims 6, 7 and 10 which are drawn to the composition of claim 1, wherein the composition has specific osmolality, zero-shear viscosity and crossover frequency, are also encompassed by this rejection, since although Yamamoto et al. is silent about the said osmolality, zero-shear viscosity and crossover frequency of their composition, their composition may well have the same or substantially close osmolality, zero-shear viscosity and crossover frequency as applicant's composition (see abstract). Claims 8, 9, 11, 12, 69, 70 which are drawn to the composition of claim 1, wherein the composition has specific viscosity, chemical scavenger including citrate and sorbitol, and pH of about 5-8, are also encompassed by this rejection, since Yamamoto et al. disclose a composition that has the same viscosity (1000-10000 cps (centipoise)), chemical scavenger (citrate) and a pH (7.4) as applicant's composition, and since Yamamoto et al.'s. disclose that sugars which includes xylitol and sorbitol can be used (see abstract).

Claim 40 is drawn to a package for a viscoelastic composition, the package comprising a syringe containing a viscoelastic composition 0.6%w/v to 4%w/v of hyaluronic acid or a salt thereof and 0.1% w/v to 2%w/v of hydroxypropylmethylcellulose, wherein the viscoelastic

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composition has a pseudoplasticity index from 160 to 5000, and a ratio of hydroxypropylmethylcellulose to hyaluronic acid or a salt thereof from 0.1 to 1.

Yamamoto et al. disclose applicants' claimed viscoelastic composition comprising water, 1.0-2.0 w/v% of hyaluronic acid or a salt thereof and 1.0-2.0 w/v% of hydroxypropylmethylcellulose, and a ratio of hydroxypropylmethylcellulose to hyaluronic acid or a salt thereof 1 (see abstract). It should be noted that the said package does not add to the patentability of the said composition. Yamamoto et al. do not explicitly disclose the physical characteristics that pertain to the pseudoplasticity index of their prepared composition. But, the silence of Yamamoto et al. do not mean that their composition do not have the same pseudoplasticity index or physical characteristics. Yamamoto et al. anticipates the claims if their composition has the same claimed pseudoplasticity index. Yamamoto et al. renders the claims as being obvious if their composition has a pseudoplasticity index that is substantially close to the pseudoplasticity index of applicant's claimed composition. Claims 41 and 42 which are drawn to the specific properties of the package comprising the composition and the intended use of the composition, is also encompassed by this rejection since the said package and intended use of the composition does not add to the patentability of the composition claimed. It should be noted that it is well settled that "intended use" of a composition or product, e.g., to force said composition through a stainless cannula, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Claims 43-44 which are drawn to the composition of claim 40, wherein the hyaluronic acid and hydroxypropylmethylcellulose have specific average molecular weights ranges, are also encompassed by this rejection, since although Yamamoto et al.'s is silent about the average

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molecular weight of hyaluronic acid and hydroxypropylmethylcellulose in their composition, their composition may well have the same or substantially close average molecular weights of hyaluronic acid and hydroxypropylmethylcellulose as applicant's composition (see abstract). Similarly, claims 47-49 and 51 which are drawn to the composition of claim 40, wherein the composition has specific osmolality, zero-shear viscosity and crossover frequency, are also encompassed by this rejection, since although Yamamoto et al.'s is silent about the said osmolality, zero-shear viscosity, medium-shear viscosity and crossover frequency of their composition, their composition may well have the same or substantially close osmolality, zero-shear viscosity, medium-shear viscosity and crossover frequency as applicant's composition (see abstract). Claims 45 and 46 which are drawn to the composition of claim 40, wherein the composition has specific %w/v of hyaluronic acid and hydroxypropylmethyl-cellulose, are also encompassed by this rejection, since Yamamoto et al. disclose a composition that has the same %w/v of hyaluronic acid and hydroxypropylmethylcellulose (1.0-2.0 w/v%) (see abstract). Claims 50, 52, 53, 70, 73 which are drawn to the composition of claim 40, wherein the composition has specific viscosity and pH of about 6.5-7.5, are also encompassed by this rejection, since Yamamoto et al.'s. disclose a composition that has the same viscosity (1000-10000 cps (centipoise)) and a pH (7.4) as applicant's composition, and since Yamamoto et al. disclose that sugars which includes xylitol and sorbitol can be used (see abstract).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the

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examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

A handwritten signature in black ink, appearing to read 'SAJ 12/8/06', is written over a horizontal line.

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

December 8, 2006.